

WALSH
PIZZI
O'REILLY
FALANGA

THREE GATEWAY CENTER
100 Mulberry Street, 15th Floor
Newark, NJ 07102
T: 973.757.1100
F: 973.757.1090
WALSH.LAW

Liza M. Walsh
Direct Dial: (973) 757-1101
lwalsh@walsh.law

October 25, 2021

[REDACTED]

VIA ECF

Honorable Zahid N. Quraishi, U.S.D.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

**Re: *Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc.*,
Civil Action No: 3:20-18319 (ZNQ-DEA)**

Dear Judge Quraishi:

Consistent with the Court's Order (D.I. 37), the parties hereby submit a joint letter apprising the Court as to the status of the parties' applications before the FDA and their related suit in the District of Delaware.

The Parties' FDA Applications

Pending before the FDA is Defendant Eagle Pharmaceuticals, Inc.'s ("Eagle") Abbreviated New Drug Application No. 211538 ("Eagle's ANDA") to market a generic version of Par's Original Vasostrict product. The FDA is currently reviewing Eagle's ANDA, and a response, which could be approval, is expected on or before December 15, 2021.

[REDACTED]

Pending before FDA is Plaintiff Par Sterile Products NDA 204485/S-018 application for a post-approval supplement (the "PAS") to amend the NDA for Vasostrict® to add information relating to dosing by genotype. The application remains pending, but has not yet been approved.

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The Parties' Delaware Litigation

On August 31, 2021, the U.S. District Court for the District of Delaware issued an opinion holding that Eagle's ANDA, as it stands, would not infringe Par's asserted patents (U.S. Patent Nos. 9,744,209 and 9,750,785). *See Par Pharms., Inc. v. Eagle Pharms, Inc.*, C.A. No. 1:18-cv-00823-CFC-JLH, ECF No. 300 (D. Del. Aug. 31, 2021). On September 16, 2021, the Court entered a Final Judgment of non-infringement. *Par Pharms.*, ECF No. 305 (D. Del. Sept. 16, 2021). On September 22, 2021, Par filed its notice of appeal, which has been docketed and is pending before the U.S. Court of Appeals for the Federal Circuit. *See Par Pharms.*, C.A. No. 2021-2342 (Fed. Cir.).

Respectfully submitted,

Liza M. Walsh

Liza M. Walsh

cc: All Counsel of Record (*via ECF and Email*)